UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 3, 2019

MEMORANDUM

Subject: Efficacy Review for S&S Sanitizer; EPA File No. 1677-EAN; DP Barcode: D452216; E-Sub #: 37629; Submission #: 1032592.

From: Ibrahim Laniyan, Ph.D.
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Thru: Tajah L. Blackburn, PhD, MPH.
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Date Signed: 8/29/19

To: Jacqueline Hardy RM 34 / Srinivas Gowda
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102

Formulation from the Label:

Active Ingredients	% by wt.
Dodecylbenzenesulfonic acid	12.8 %
L-Lactic acid	34.1 %
Inert Ingredients:	53.1 %
Total	100.0 %

I. BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid.

Submission type: New end use product

Currently registered efficacy claim(s): N/A

Requested action(s): Register as disinfectant (bactericide and virucide) and sanitizer (food and non-food contact)

Documents considered in this review:

- Letter from applicant to EPA dated March 22, 2019
- Application for Pesticide (EPA form 8570-1) dated March 8, 2019.
- Confidential Statement of Formula (EPA form 8570-4) dated February 27, 2019
- Certification with Respect to Citation of Data (EPA Form 8570-34) dated March 8, 2019
- Data Matrix (EPA Form 8570-35) dated February 27, 2019
- 12 efficacy studies (MRID nos. 508159-07 to 508159-18)
- Proposed label dated March 18, 2019.

II. PROPOSED DIRECTIONS FOR USE

To SANITIZE food utensils, food serving equipment, dishes, glasses, bar glasses, and silverware in a (two-) (and) (or) three-compartment sink:
1. Prior to application, thoroughly wash or flush objects (with) (this product) (insert product name) (or) (a) (suitable) (detergent) (or) (a compatible cleaner) followed by a potable water rinse. (If (this product) (insert product name) is used as a detergent at 0.27 - 0.55 fl. oz./gal, no rinse is required prior to sanitizing).
2. Dilute (this product) to 0.27 - 0.55 fl. oz./gal (in up to 500 ppm hard water). Expose all surfaces to the sanitizing solution by immersion for a period of not less than 1 minute.
3. Allow to drain thoroughly to air dry, no rinse required.

(FOR) CLEANING AND SANITIZING (FOR) HARD, NON-POROUS FOOD CONTACT SURFACES¥:
-or-
TO SANITIZE (HARD, NON-POROUS FOOD CONTACT SURFACES):
1. Dilute (this product) (insert product name) to 0.27 - 0.55 fl. oz./gal (in up to 500 ppm hard water).
2. Heavily soiled surfaces must be pre-cleaned (with) (this product) (or) (a suitable cleaner) prior to sanitizing. (When) (this product) (insert product name) (is) used at this concentration, no rinse is required prior to sanitizing.)
3. To sanitize, apply (this product) (insert product name) to the surface (by) (pouring), (squirting), (or) with a cloth, disposable wipe, mop, or sprayer (device), wetting the surface. For spray application, spray 6-8 inches from the surface. (Rub (wet surface) with clean brush, or cloth).
4. Allow surface to remain wet for (not less than) 1 minute.
5. Allow to (drain and) air dry. ((No (water) rinse required). (A water rinse is not required). (If desired, wipe with a (lint free) cloth or paper towel after (1)(one-)minute contact time).
6. Fresh solution must be prepared daily, when the use solution becomes visibly dirty or when the (use) solution tests below sanitizing concentration range.

TO DISINFECT HARD, NON-POROUS (FOOD AND NON-FOOD CONTACT) SURFACES:
1. Dilute (this product) (insert product name) to 1.37 – 1.41 fl. oz./gal (in up to 400 ppm hard water).
2. Surfaces must be pre-cleaned (with) (this product) (or) (a suitable cleaner) prior to disinfecting.

3. To disinfect, apply (this product) (insert product name) to surface by (flushing), (mopping), (sponging), (wiping), (or) (by) (hand pump) (coarse) (trigger) (spray) (6-8 inches from surface) to wet surface.
4. Allow surface to remain wet for 10 minutes.
5. Wipe (dry) with a (cloth), (paper towel), (clean mop), (wet vacuum pickup), or allow to air dry. No rinse required for non-food contact surfaces. Rinse food contact surfaces with potable water.
6. Fresh solution must be prepared daily, when the use solution becomes visibly dirty or when the (use) solution tests below disinfection concentration range.

III. STUDY SUMMARIES

1.	MRID	508159-07	Study Completion Date:	March 14, 2019
Study Objective/Title		CW32A Food Contact Sanitizing Efficacy		
Testing Lab / Lab Study ID		Ecolab, Inc. / 1800073		
Test organism(s) ☐ 1 ☒ 2 ☐ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229)		
Test Method		Ecolab Microbiological Services SOP MS009-26; Germicidal & Detergent Sanitizing Action of Disinfectants (*copy provided*)		
Application Method		1.0 mL of the test system suspension was added to 99 mL of the diluted test substance.		
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871		
	Lots ☐ 1 ☐ 2 ☒ 3	P081381, P081581, and P081781		
	Preparation	0.25 oz/gallon to at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and 650 ppm Lactic Acid in 500 ppm synthetic hard water		
Soil load		NA		
Carrier type, # per lot		N/A		
Test conditions	**Contact time**	30 seconds	**Temp** 25 ± 1 °C	**RH** -
Neutralizer		DE Broth		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		-		

2.	MRID	508159-08	Study Completion Date:	March 14, 2019
Study Objective/Title		CW32A Supplemental Food Contact Sanitizing Efficacy		
Testing Lab / Lab Study ID		Ecolab, Inc. / 1800075		
Test organism(s) ☐ 1 ☒ 2 ☐ 3 ☐ 4+		*Listeria monocytogenes* (ATCC 19117) and *Salmonella enterica* (ATCC 10708)		
Test Method		Ecolab Microbiological Services SOP MS009-26; Germicidal & Detergent Sanitizing Action of Disinfectants (*copy provided*)		
Application Method		1.0 mL of the test system suspension was added to 99 mL of the diluted test substance.		
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871		
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781		
	Preparation	0.25 oz/gallon to at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and 650 ppm Lactic Acid in 500 ppm synthetic hard water		
Soil load		NA		
Carrier type, # per lot		N/A		
Test conditions	**Contact time**	30 seconds	**Temp** 25±1°C	**RH** -
Neutralizer		DE Broth		
Reviewer comments		-		

(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	

3.	**MRID**	508159-09	**Study Completion Date:**		March 14, 2019		
Study Objective/Title		CW32A Supplemental Food Contact Sanitizing Efficacy					
Testing Lab / Lab Study ID		Ecolab, Inc. / 1800074					
Test organism(s) ☐ 1 ☒ 2 ☐ 3 ☐ 4+		*Escherichia coli* O157:H7 (ATCC 35150) and *Yersinia enterocolitica* (ATCC 23715)					
Test Method		Ecolab Microbiological Services SOP MS009-26; Germicidal & Detergent Sanitizing Action of Disinfectants (*copy provided*)					
Application Method		1.0 mL of the test system suspension was added to 99 mL of the diluted test substance.					
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871					
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781					
	Preparation	0.25 oz/gallon to at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and 650 ppm Lactic Acid in 500 ppm synthetic hard water					
Soil load		NA					
Carrier type, # per lot		N/A					
Test conditions		**Contact time**	30 seconds	**Temp**	25±1°C	**RH**	-
Neutralizer		DE Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		-					

4.	**MRID**	508159-10	**Study Completion Date:**		March 14, 2019		
Study Objective/Title		CW32A Supplemental Food Contact Sanitizing Efficacy					
Testing Lab / Lab Study ID		Ecolab, Inc. / 1800089					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Campylobacter jejuni* (ATCC 33291)					
Test Method		Ecolab Microbiological Services SOP MS009-26; Germicidal & Detergent Sanitizing Action of Disinfectants (*copy provided*)					
Application Method		1.0 mL of the test system suspension was added to 99 mL of the diluted test substance.					
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871					
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781					
	Preparation	0.25 oz/gallon to at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and 650 ppm Lactic Acid in 500 ppm synthetic hard water					
Soil load		NA					
Carrier type, # per lot		N/A					
Test conditions		**Contact time**	30 seconds	**Temp**	25±1°C	**RH**	-
Neutralizer		DE Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		-					

5.	**MRID**	508159-11	**Study Completion Date:**	March 14, 2019
Study Objective/Title		CW32A Supplemental Food Contact Sanitizing Efficacy		
Testing Lab / Lab Study ID		Ecolab, Inc. / 1800076		

Test organism(s) ☐ 1 ☐ 2 ☐ 3 ☒ 4+		*Shigella flexneri* (ATCC 29508), *Shigella sonnei* (ATCC 11060), *Cronobacter sakazakii* (ATCC 12868), and *Staphylococcus aureus*- CA-MRSA USA 400 (ATCC BAA-1683)					
Test Method		Ecolab Microbiological Services SOP MS009-26; Germicidal & Detergent Sanitizing Action of Disinfectants (*copy provided*)					
Application Method		1.0 mL of the test system suspension was added to 99 mL of the diluted test substance.					
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871					
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781					
	Preparation	0.25 oz/gallon to at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and 650 ppm Lactic Acid in 500 ppm synthetic hard water					
Soil load		NA					
Carrier type, # per lot		N/A					
Test conditions		**Contact time**	30 seconds	**Temp**	25±1°C	**RH**	-
Neutralizer		DE Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic susceptibility testing was performed on *Staphylococcus aureus* - CA-MRSA USA 400 ATCC BAA-1683 using the disk diffusion method in MS111-08; *Antibiotic Susceptibility Tests* to confirm antibiotic resistance. Drug resistance was confirmed using 1 µg Oxacillin disks.					

6.	**MRID**	508159-12	**Study Completion Date:**	March 15, 2019
Study Objective/Title		CW32A Non-Food Contact Sanitizing Efficacy		
Testing Lab / Lab Study ID		Ecolab, Inc. / 1800102		
Test organism(s) ☐ 1 ☒ 2 ☐ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)		
Test Method		Ecolab Microbiological Services SOP MS016-30, Non-Food Contact Sanitizer Test Method (*copy provided*)		
Application Method		Carriers were individually exposed to a 5.0 ml aliquot of the use dilution		
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871		
	Lots ☐ 1 ☐ 2 ☒ 3	P081381, P081581, and P081781		
	Preparation	0.27 oz/gallon to at or below the lower limit of 270 ppm Dodecylbenzene Sulfonic Acid (LAS) and to at or below the lower limit of 700 ppm Lactic Acid in 500 ppm synthetic hard water.		
Soil load		5% Fetal bovine serum (FBS)		
Carrier type, # per lot		1-inch square stainless steel / 5 carriers/replicates per organism and per lot		
Test conditions		**Contact time**	5 minutes	**Temp** Ambient **RH** -
Neutralizer		DE Broth		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carriers were inoculated with 0.01 mL for *Staphylococcus aureus* (ATCC 6538) and 0.02 mL for *Enterobacter aerogenes* (ATCC 13048). Carriers were then dried with the Petri dish lids slightly ajar in a desiccator containing 86.5% glycerin in a 35 ± 2°C incubator for 20-40 minutes.		

7.	**MRID**	508159-13	**Study Completion Date:**	March 15, 2019
Study Objective/Tittle		CW32A Hospital Disinfection Efficacy		
Testing Lab, Lab Study ID		Ecolab, Inc. / 1800087		
Test organism(s) ☐ 1 ☐ 2 ☒ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella enterica* (ATCC 10708)		
Test Method		Ecolab Microbiological Services SOP MS003-33; Use Dilution Method (*copy provided*)		
Application Method		Carriers were individually exposed to a 10.0 ml aliquot of the use dilution		
	Name/ID	CW32A (EPA Registration No.1677-EAN), formula code 919871		
	Lots	P081381, P081581, and P081781		

Test Substance Preparation	☐ 1 ☐ 2 ☒ 3						
	Preparation	1.37 oz/gallon resulting in the active ingredients at or below the lower limit of 1380 ppm Dodecylbenzene Sulfonic Acid and at or below the lower limit of 3570 ppm Lactic Acid when diluted in 400 ppm synthetic hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Polished stainless steel penicillin cup carriers (8±1mm outside diameter, 6±1mm inside diameter, length 10±1mm, composed of 304 stainless steel) / 60 per batch and per organism					
Test conditions		**Contact time**	10 minutes	**Temp**	Ambient	**RH**	-
Neutralizer		Letheen Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Carriers were immersed for 15 min at a rate of 1 carrier per 1 ml culture; and dried for 40 minutes at 35±2°C. Due to efficacy failures of *Salmonella enterica* ATCC 10708 at 1.31oz/gallon and 1.34 oz/gallon, the final test substance concentration was 1.37 oz/gallon					

8.	**MRID**	508159-14	**Study Completion Date:**			March 14, 2019	
Study Objective / Tittle		CW32A Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Feline Calicivirus as a surrogate for Norovirus					
Testing Lab, Lab Study ID		Ecolab, Inc. / 1800061					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Feline Calicivirus, strain F-9 (ATCC VR-782)					
Indicator Cell Culture		CRFK cells were obtained from Quidel, Athens, Ohio.					
Test Method		Ecolab Microbiological Services SOP MS505-12; Virucidal Efficacy Assay for Hard Surfaces. (*copy provided*)					
Application Method		A 2 mL aliquot of each batch of test substance use-solution was dispensed onto the dried virus film in a glass Petri dish with a micropipettor					
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871					
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781					
	Preparation	0.25 oz/gallon resulting in the active ingredient at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and at or below the lower limit of 650 ppm Lactic Acid when diluted in 500 ppm synthetic hard water					
Soil load		No Soil					
Carrier type, # per lot		two dried virus films per batch					
Test conditions		**Contact time**	30 seconds	**Temp**	Ambient	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		A 0.2 mL aliquot of the virus was evenly spread on the bottom of 100 x 15 mm glass Petri dishes. The Petri dishes were dried in a humidity chamber for 20 - 22 minutes (until visibly dry) with the lids removed.					

9.	**MRID**	508159-15	**Study Completion Date:**			March 14, 2019	
Study Objective / Tittle		CW32A Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Influenza A (H1N1)					
Testing Lab, Lab Study ID		Ecolab, Inc. / 1800085					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Influenza A (H1N1) (ATCC VR-1736)					
Indicator Cell Culture		RMK cells were obtained from Quidel (Diagnostic Hybrids), Athens, Ohio.					
Test Method		Ecolab Microbiological Services SOP MS505-12; Virucidal Efficacy Assay for Hard Surfaces. (*copy provided*)					
Application Method		A 2 mL aliquot of each batch of test substance use-solution was dispensed onto the dried virus film in a glass Petri dish with a micropipettor					
	Name/ID	CW32A (EPA Registration No.1677-EAN), formula code 919871					
	Lots	P081581 and P081781					

Test Substance Preparation	☐ 1 ☒ 2 ☐ 3						
	Preparation	0.25 oz/gallon resulting in the active ingredient at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and at or below the lower limit of 650 ppm Lactic Acid when diluted in 500 ppm synthetic hard water					
Soil load		No Soil					
Carrier type, # per lot		one dried virus film per batch					
Test conditions		**Contact time**	30 seconds	**Temp**	Ambient	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		A 0.2 mL aliquot of the virus was evenly spread on the bottom of 100 x 15 mm glass Petri dishes. The Petri dishes were dried in a humidity chamber for 13 minutes (until visibly dry) with the lids removed.					

10.	**MRID**	508159-16	**Study Completion Date:**		March 14, 2019
Study Objective / Tittle		CW32A Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Influenza A (H3N2)			
Testing Lab, Lab Study ID		Ecolab, Inc. / 1800083			
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Influenza A (H3N2), strain A/Hong Kong/8/68 (ATCC VR-544)			
Indicator Cell Culture		RMK cells were obtained from Quidel (Diagnostic Hybrids), Athens, Ohio.			
Test Method		Ecolab Microbiological Services SOP MS505-12; Virucidal Efficacy Assay for Hard Surfaces. (*copy provided*)			
Application Method		A 2 mL aliquot of each batch of test substance use-solution was dispensed onto the dried virus film in a glass Petri dish with a micropipettor			
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871			
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781			
	Preparation	0.25 oz/gallon resulting in the active ingredient at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and at or below the lower limit of 650 ppm Lactic Acid when diluted in 500 ppm synthetic hard water			
Soil load		No Soil			
Carrier type, # per lot		one dried virus film per batch			
Test conditions		**Contact time**	30 seconds	**Temp**	Ambient	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		A 0.2 mL aliquot of the virus was evenly spread on the bottom of 100 x 15 mm glass Petri dishes. The Petri dishes were dried in a humidity chamber for 17-18 minutes (until visibly dry) with the lids removed.			

11.	**MRID**	508159-17	**Study Completion Date:**		March 14, 2019
Study Objective / Tittle		CW32A Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Influenza B			
Testing Lab, Lab Study ID		Ecolab, Inc. / 1800084			
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Influenza B strain: B/Lee/40 (ATCC VR-1535)			
Indicator Cell Culture		RMK cells were obtained from Quidel (Diagnostic Hybrids), Athens, Ohio.			
Test Method		Ecolab Microbiological Services SOP MS505-12; Virucidal Efficacy Assay for Hard Surfaces. (*copy provided*)			
Application Method		A 2 mL aliquot of each batch of test substance use-solution was dispensed onto the dried virus film in a glass Petri dish with a micropipettor			
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871			
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781			

	Preparation	0.25 oz/gallon resulting in the active ingredient at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and at or below the lower limit of 650 ppm Lactic Acid when diluted in 500 ppm synthetic hard water					
Soil load		No Soil					
Carrier type, # per lot		one dried virus film per batch					
Test conditions		**Contact time**	30 seconds	**Temp**	Ambient	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		A 0.2 mL aliquot of the virus was evenly spread on the bottom of 100 x 15 mm glass Petri dishes. The Petri dishes were dried in a humidity chamber for 15-17 minutes (until visibly dry) with the lids removed.					

12.	**MRID**	508159-18	**Study Completion Date:**		March 15, 2019		
Study Objective / Tittle		CW32A Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Virus: Human Rhinovirus 37					
Testing Lab, Lab Study ID		Ecolab, Inc. / 1800086					
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		Human Rhinovirus 37 strain 151-1 (ATCC VR-1607)					
Indicator Cell Culture		H1Hela cells (ATCC CRL-1958)					
Test Method		Ecolab Microbiological Services SOP MS505-12; Virucidal Efficacy Assay for Hard Surfaces. (*copy provided*)					
Application Method		A 2 mL aliquot of each batch of test substance use-solution was dispensed onto the dried virus film in a glass Petri dish with a micropipettor					
Test Substance Preparation	**Name/ID**	CW32A (EPA Registration No.1677-EAN), formula code 919871					
	Lots ☐ 1 ☒ 2 ☐ 3	P081581 and P081781					
	Preparation	0.25 oz/gallon resulting in the active ingredient at or below the lower limit of 250 ppm Dodecylbenzene Sulfonic Acid (LAS) and at or below the lower limit of 650 ppm Lactic Acid when diluted in 500 ppm synthetic hard water					
Soil load		5% FBS					
Carrier type, # per lot		one dried virus film per batch					
Test conditions		**Contact time**	30 seconds	**Temp**	Ambient	**RH**	
Neutralizer		Sephadex LH-20 gel filtration column					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		A 0.2 mL aliquot of the virus was evenly spread on the bottom of 100 x 15 mm glass Petri dishes. The Petri dishes were dried in a humidity chamber for 20-23 minutes (until visibly dry) with the lids removed.					

V. RESULTS

MRID Number	Organism	Results (CFU/mL)			Log_{10} Reduction
		Lots	Survivors	Control	
0.25 fl.oz./gal of 500ppm AOAC Hard water – No Soil – 30 seconds contact time – 25±1°C.					
508159-07	*Escherichia coli* (ATCC 11229)	P081381	<1.8 X 10^1	5.5 x 10^7	>6.48
		P081581	<1.8 X 10^1		>6.48
		P081781	<1.8 X 10^1		>6.48
	Staphylococcus aureus (ATCC 6538)	P081381	<1.8 X 10^1	6.4 x 10^7	>6.55
		P081581	<1.8 X 10^1		>6.55
		P081781	<1.8 X 10^1		>6.55
508159-08	*Listeria monocytogenes* (ATCC 19117)	P081581	<1.8 X 10^1	6.6 x 10^7	>6.56
		P081781	<1.8 X 10^1		>6.56
	Salmonella enterica (ATCC 10708)	P081581	<1.8 X 10^1	7.8 x 10^7	>6.63
		P081781	<1.8 X 10^1		>6.63
508159-09		P081581	<1.8 X 10^1	7.1 x 10^7	>6.59

	Escherichia coli O157:H7 (ATCC 35150)	P081781	<1.8 X 10^1		>6.59
	Yersinia enterocolitica (ATCC 23715)	P081581	<1.8 X 10^1	1.1 x 10^8	>6.78
		P081781	<1.8 X 10^1		>6.78
508159-10	*Campylobacter jejuni* (ATCC 33291)	P081581	<1.8 X 10^1	2.5 x 10^7	>6.13
		P081781	<1.8 X 10^1		>6.13
508159-11	*Shigella flexneri* (ATCC 29508)	P081581	<1.8 X 10^1	2.0 x 10^7	>6.04
		P081781	<1.8 X 10^1		>6.04
	Shigella sonnei (ATCC 11060)	P081581	<1.8 X 10^1	2.5 x 10^7	>6.15
		P081781	<1.8 X 10^1		>6.15
	Cronobacter sakazakii (ATCC 12868)	P081581	<1.8 X 10^1	4.1 x 10^7	>6.35
		P081781	<1.8 X 10^1		>6.35
	Staphylococcus aureus - CA-MRSA USA 400 (ATCC BAA-1683)	P081581	<1.8 X 10^1	3.8 x 10^7	>6.32
		P081781	<1.8 X 10^1		>6.32
			Geometric Mean		**Percent Reduction**
0.27 fl.oz./gal of 500ppm AOAC Hard water – 5% FBS – 5 minutes contact time – Ambient room temp.					
508159-12	*Enterobacter aerogenes* (ATCC 13048)	P081381	<6.8 X 10^2	4.2 x 10^6	>99.984
		P081581	<2.7 X 10^1		>99.999
		P081781	<7.2 X 10^2		>99.983
	Staphylococcus aureus (ATCC 6538)	P081381	<3.8 X 10^2	3.0 x 10^6	>99.987
		P081581	<1.0 X 10^3		>99.967
		P081781	<4.1 X 10^2		>99.986

MRID Number	Organism	Contact Time	No. Exhibiting Growth/Total No. Tested			Dried Carrier Count (Log_{10}/ carrier)
			Lot No. P081381	Lot No. P081581	Lot No. P081781	
1.31 fl.oz./gal of 400ppm AOAC Hard water – 5% FBS – 10 minutes – 20±1°C ***RPT1: 1.34 fl.oz./gal of 400ppm AOAC Hard water – 5% FBS – 10 minutes – 20±1°C*** ***RPT2: 1.37 fl.oz./gal of 400ppm AOAC Hard water – 5% FBS – 10 minutes – 20±1°C***						
508159-13	*Staphylococcus aureus* (ATCC 6538)	10 minutes	2/60	1/60	0/60	6.68 / 6.89 / 6.60
	Pseudomonas aeruginosa (ATCC 15442)		3/60	0/60	0/60	6.61 / 6.91 / 6.53
	Salmonella enterica (ATCC 10708)		0/60	3/60 *RPT1*: 3/60 *RPT2*: 0/60	3/60 *RPT1*: 1/60	6.02 / 5.62 / 5.62 *RPT1*: 5.87 *RPT2*: 5.73

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/Carrier)
			Lot P081581	Lot P081781	
0.25 fl.oz./gal of 500ppm AOAC Hard water – No Soil – 30 seconds contact time – Ambient room temp.					
508159-14	Feline Calicivirus, strain F-9 (ATCC VR-782)	10^{-1} to 10^{-3} dilutions	Complete inactivation	Complete inactivation	$10^{7.05}$
		$TCID_{50}$/Carrier	$\leq 10^{0.8}$	$\leq 10^{0.8}$	
		Log reduction	$\geq$6.25 log_{10}	$\geq$6.25 log_{10}	
508159-15	Influenza A (H1N1) (ATCC VR-1736)	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{4.80}$
		$TCID_{50}$/Carrier	$\leq 10^{0.8}$	$\leq 10^{0.8}$	
		Log reduction	$\geq$4.0 log_{10}	$\geq$4.0 log_{10}	
508159-16	Influenza A (H3N2), strain A/Hong	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{5.55}$
		$TCID_{50}$/Carrier	$\leq 10^{0.8}$	$\leq 10^{0.8}$	

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/Carrier)
			Lot P081581	Lot P081781	
	Kong/8/68 (ATCC VR-544)	Log reduction	≥4.75 log_{10}	≥4.75 log_{10}	
508159-17	Influenza B strain: B/Lee/40 (ATCC VR-1535)	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{5.30}$
		$TCID_{50}$/Carrier	$\leq 10^{0.8}$	$\leq 10^{0.8}$	
		Log reduction	≥4.50 log_{10}	≥4.50 log_{10}	
0.25 fl.oz./gal of 500ppm AOAC Hard water – 5% FBS – 30 seconds contact time – Ambient room temp.					
508159-17	Human Rhinovirus 37 strain 151-1 (ATCC VR-1607)	10^{-1} to 10^{-5} dilutions	Complete inactivation	Complete inactivation	$10^{5.30}$
		$TCID_{50}$/Carrier	$\leq 10^{0.8}$	$\leq 10^{0.8}$	
		Log reduction	≥4.50 log_{10}	≥4.50 log_{10}	

VI. CONCLUSIONS

MRID	Claim	Surface Types	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
508159-07-508159-11	Food Contact Sanitization	Hard Non-Porous	Dilution 0.25 fl.oz./gal	30 seconds	-	500 ppm AOAC Hard Water	*Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11229), *Listeria monocytogenes* (ATCC 19117), *Salmonella enterica* (ATCC 10708), *Escherichia coli* O157:H7 (ATCC 35150), *Yersinia enterocolitica* (ATCC 23715) *Campylobacter jejuni* (ATCC 33291), *Shigella flexneri* (ATCC 29508), *Shigella sonnei* (ATCC 11060), *Cronobacter sakazakii* (ATCC 12868), *Staphylococcus aureus* - CA-MRSA USA 400 (ATCC BAA-1683)	Yes
508159-12	Non-Food Contact Sanitization	Hard Non-Porous	Dilution 0.27 fl.oz./gal	5 minutes	5%	500 ppm AOAC Hard Water	*Staphylococcus aureus* (ATCC 6538) *Enterobacter aerogenes* (ATCC 13048)	Yes
508159-13	Disinfectant Bactericidal	Hard Non-Porous	Dilution 1.37 fl.oz./gal	10 minutes	5%	400 ppm AOAC Hard Water	*Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella*	Yes

							enterica (ATCC 10708)	
508159-14 - 508159-18	Disinfectant Virucidal	Hard Non-Porous	Dilution 0.25 fl.oz./gal	30 seconds	-	500 ppm AOAC Hard Water	Feline Calicivirus, strain F-9 (ATCC VR-782) Influenza A (H1N1) (ATCC VR-1736) Influenza A (H3N2), strain A/Hong Kong/8/68 (ATCC VR-544) Influenza B strain: B/Lee/40 (ATCC VR-1535)	**Yes**
508159-18	Disinfectant Virucidal	Hard Non-Porous	Dilution 0.25 fl.oz./gal	30 seconds	5%	500 ppm AOAC Hard Water	Human Rhinovirus 37 strain 151-1 (ATCC VR-1607)	**Yes**

VII. LABEL COMMENTS

Proposed Label dated March 18, 2019

1. The proposed label claims that the product, S&S Sanitizer (EPA File No. 1677-EAN), is an effective disinfectant on visibly clean or pre-cleaned hard non-porous surfaces, when diluted 1.37 fl. oz./gallon, in 10 minutes contact time; **are acceptable.**

2. The proposed label claims that the product, S&S Sanitizer (EPA File No. 1677-EAN), is an effective disinfectant in spray application only, on visibly clean or pre-cleaned hard non-porous surfaces, when diluted 0.52 fl. oz./gallon, in 8 minutes contact time; **are acceptable. Data supporting those claims are submitted under MRID # 50816006. Applicable to toilette seat cover and dried exterior surfaces, but not to toilette bowl.**

3. The proposed label claims that the product, S&S Sanitizer (EPA File No. 1677-EAN), is an effective food-contact sanitizer on hard non-porous surfaces, when diluted 0.27 fl. oz./gallon, in 1-minute contact time; **are acceptable**.

4. The proposed label claims that the product, S&S Sanitizer (EPA File No. 1677-EAN), is an effective non-food contact sanitizer on visibly clean or pre-cleaned hard non-porous surfaces, when diluted 0.27 fl. oz./gallon, in 5 minutes contact time; **are acceptable.**

5. The proposed label claims that the product, S&S Sanitizer (EPA File No. 1677-EAN), is an effective virucidal on pre-cleaned hard non-porous surfaces, when diluted 0.27 fl. oz./gallon, in 30 minutes contact time; **are acceptable.**

6. Registrant must make the following changes to the proposed label:

- On page 6, remove the claim “Protects employees”
- On pages 6 and 9, remove the claim “Promotes food safety”
- On page 7, remove the claim “Germ-fighting”
- On page 8, remove the claim “Helps enhance food safety…”
- On page 9, remove the claim “Promotes quality assurance”
- On page 9, remove the claim “hazardous microorganisms”
- On page 9, remove references to “toxins” and “support the rapid development”

- On page 9, remove optional language pertaining to disease-causing organisms
- On page 9, remove the claim for “Improved safety compliance”
- On page 9, there is no such thing as broad-spectrum sanitizer. Remove claim.
- On page 10, “glazed” for tiles is not optional language
- On page 11, “vinyl” and “plastic” is not optional language for upholstery
- On page 11, “finished” is not optional language for woodwork
- On page 10, add “on treated surfaces” to “(This product) (insert product name) (Helps) (Reduce)(s) the risk of cross-contamination”.
- The terms “Eliminate” must be removed from sanitization and disinfection claims because it is synonym of sterilize.